

**REMARKS**

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

***Status of the Claims***

In the present Amendment, claim 2 has been amended. Also, claims 29-30 have been added. Further, claims 5 and 24-27 have been canceled, and claims 1, 3, 6, 7, 11 and 16-23 were previously canceled, without prejudice or disclaimer of the subject matter contained therein. Thus, claims 2, 4, 8-10, 12-15 and 28-30 are pending in the present application.

No new matter has been added by way of the amendment to claim 2. The amendment to claim 2 has support in originally filed claim 1 as well as in the present specification at least in paragraph [0015], [0023], [0033], and [0034], as well as paragraphs [0007], [0008], [0011], [0012], etc.

No new matter has been added with claims 29-30. For claim 29, Applicants note, for example, paragraphs [0027], [0028] and [0044]. For claim 30, see, e.g., paragraphs [0022], [0023] and [0044].

Applicants note that claim 2 is directed to the polymer (the biocompatible component) being covalently bonded to the surface of the diamond-like carbon ("DLC") film. The present specification describes forming a polymerization starting point on the surface of the DLC film. This is accomplished by activating the DLC surface to form a reactive region (see, e.g., paragraph [0022]). Then, for example, the reactive region is modified by a further reaction with a molecule having an oxygen (see, e.g., paragraph [0027]) or forming some radical thereon (see, e.g.,

paragraph [0043]. Claim 29 is an example of a hydroxyl group that is formed, which can serve as the polymerization starting point on the surface of the DLC film. Thus, the formation of the polymerization starting point on the surface of the DLC film leads to the polymer covalently bonding to the surface of the DLC film. As a result, the claimed product has good adhesion between the DLC film and the biocompatible component, as well as excellent durability for the base material due to the hard, dense coating of the DLC film, and at the same time has desirable polymeric characteristics.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

***Substance of the Interview***

Applicants thank the Examiner and Supervisory Patent Examiner (SPE) for their time, helpfulness and courtesies extended to Applicants' representative during the Interview of June 17, 2009. The assistance of the Examiner and SPE in advancing prosecution of the present application is greatly appreciated. In compliance with M.P.E.P. § 713.04, Applicants submit the following remarks.

The Interview Summary form amply summarizes the discussions at the Interview. Various ways of addressing the prior art rejections were discussed, and suggestions were discussed that may be drafted to cover particular aspects of the invention as not described by the prior art. In particular, Applicants' representative referred the Examiner and SPE to claim 2 as

shown herein, which distinguishes over the cited references (wherein the rejections are discussed below).

***Issues under 35 U.S.C. § 112, First Paragraph***

Claims 5 and 27 stand rejected under 35 U.S.C. § 112, first paragraph, for asserted lack of written description (see Office Action, paragraphs 3-5, pages 2-3).

Since these claims are canceled, this rejection is rendered moot. Withdrawal of this rejection is respectfully requested.

***Issues under 35 U.S.C. § 103(a)***

Claims 2, 4, 8 and 12-15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Woo ‘736** (U.S. Patent No. 6,761,736) (Office Action, paragraphs 6-12).

Also, claims 2, 4, 5 and 12-15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Steffen et al.** (*Sur. Interface Anal.*, Vol. 29, pp. 386-391 (2000)) in view of **Palmaz ‘310** (U.S. Patent No. 6,537,310 B1) (Office Action, paragraphs 13-19).

Further, claims 9 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Steffen et al.** and **Palmaz ‘310** as applied to claim 2, in further view of **Lemelson ‘570** (U.S. Patent No. 6,083,570) (Office Action, paragraphs 20-23).

In addition, claims 24 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Baselt ‘297** (U.S. Patent No. 5,981,297) (Office Action, paragraphs 24-26).

Furthermore, claims 8, 26 and 27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Steffen et al.** and **Palmaz ‘310** as applied to claim 2, in further view of **Suto**

*et al.* (*J. Bio. Chem.*, Vol. 280(3), pp. 2126-2131 (2005)) (Office Action, paragraphs 27-30).

Finally, claim 28 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over **Steffen *et al.*** and **Palmaz ‘310** as applied to claim 2, in further view of **Han ‘161** (U.S. Patent No. 6,268,161) (Office Action, paragraphs 31-34).

Applicants respectfully traverse and reconsideration is based on the following remarks. Overall, Applicants do not concede that a *prima facie* case of obviousness has been established with respect to any of the rejections.

#### The Present Invention and Its Advantages

The present invention, as recited in pending claim 2, is directed to a medical material comprising: a base material, a diamond-like carbon (DLC) film formed on a surface of the base material (e.g. a catheter; stent; artificial joint, etc.), and a biocompatible component covalently bonded to a surface of the DLC film. The mentioned biocompatible component is a polymer (see, e.g., paragraphs [0015], [0044]-[0049] of the present specification) made from vinyl monomers, vinylidene monomers, vinylene monomers or cyclic vinylene monomers (see, e.g., paragraph [0044]). The claimed medical material is made by having an activated surface of the DLC film that serves as a polymerization starting point and then covalently bonding the DLC surface to the mentioned polymeric biocompatible component (see, e.g., paragraphs [0023] and [0044]). This gives a final medical material product wherein the biocompatible component is covalently bonded to the DLC surface. Thus, the claimed product has good adhesion between the DLC film and the biocompatible component, as well as excellent durability for the base

material due to the hard, dense coating of the DLC film, and at the same time has desirable polymeric characteristics (e.g., high functionality).

The present invention solves problems known in the art, such as that described in paragraph [0007] (e.g., the biocompatible material separates from the DLC since the DLC surface is smooth and almost incapable of physical adsorption).

Claim 2 and dependent claims thereon

In responding to previous arguments, the Examiner states that claim 2 is a product-by-process claim, and that the graft polymerization will not result in a different structure than suggested by the cited references of Steffen *et al.*, Palmaz '310 and Lemelson '570 (see Office Action at paragraphs 44-46). However, Applicants note the changes to claim 2 as shown herein. Reconsideration is respectfully requested in view of the changes to claim 2 wherein the biocompatible component is covalent bonded to the DLC film.

Distinctions over Cited References and Combinations Thereof

The cited Woo '736 reference at column 6, from line 65, clearly describes: "[o]ther portions of the medical devices ... ." Thus, Woo '736 describes a medical device which has a part covered with a DLC film and another part covered with a biocompatible material. This structure is quite different from the medical material of claim 2 which includes the polymer (biocompatible component) covalently bonded to a DLC film that is formed on a base material. And as the M.P.E.P. directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See M.P.E.P. § 2143.03. Also, Woo

'736 fails to teach or suggest bonding a polymerization starting end of a biocompatible component bound to the polymerization starting point on the surface of a DLC film. Applicants note that one of the *Graham* factors is ascertaining the differences between the prior art and the claims that are at issue. *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Regarding the rejections citing Steffen *et al.* as a primary reference, this article describes fixing heparin to a DLC film using  $\text{NaBH}_3\text{CN}$ . In this method, the reducing end of heparin is bonded to the DLC film. As such, since the method described in Steffen *et al.* uses  $\text{NaBH}_3\text{CN}$ , its method is only applicable to molecules having reducing ends, such as sugars. In other words, when the Steffen *et al.* method is used, a polymer which does not have a reducing end cannot be immobilized. Therefore, Steffen *et al.* is quite different from the structure recited in pending claim 2 where the biocompatible component which is a polymer of vinyl monomers, etc., is covalently bonded to the DLC film.

The other cited references are also deficient in disclosing all claimed features. Palmaz '310 fail to teach or suggest covalently bonding a polymer to a DLC film formed on a surface of a medical device. Therefore, any combination of Steffen *et al.* with Palmaz '310 would not arrive at the structure of claim 2 where the polymerization starting end of the biocompatible component composed of a polymer of vinyl monomers, or the like, is bonded to the DLC film. Applicants note that under *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993) and *Ex parte Gerlach*, 212 USPQ 471 (BPAI 1980), the Examiner cannot equate that which is within the capabilities of one skilled in the art ("one of ordinary skill in the art could adjust the parameters") with obviousness.

Further, Applicants note the differences between the structure where monomers are polymerized on the surface of the DLC film to fix a polymer to the DLC film (see pending claim 2) and the structure where heparin is bonded to the surface of the DLC film using  $\text{NaBH}_3\text{CN}$  (e.g., Steffen *et al.*). In consideration of how a reference such as Palmaz '310 fails to describe covalent bonding between the surface of the DLC film and biocompatible component as claimed, a person somehow combining Steffen *et al.* with Palmaz '310 would not arrive at the structure where the polymeric biocompatible component is covalently bonded to the surface of the DLC film.

Regarding the fifth rejection, the citation of the secondary reference of Suto *et al.* does not make the rejection of claim 8 (in view of Steffen *et al.*, Palmaz '310 and Suto *et al.*) any more proper.

The rejection of Baselt '297 is rendered moot with the cancellation of the disputed claims. Further, the subject matter of Baselt '297 is directed to immunoassays, wherein using something other than antibodies as binding molecules cannot be considered based on such disclosure. Therefore, Baselt '297 is essentially irrelevant to the present invention as recited in pending claim 2.

Applicants also request favorable consideration of new claims 29 and 30. For instance, in claim 30, the polymer is a chain polymer of vinyl monomers or the like, and one end of the chain polymer is bonded to the surface of the DLC film. This structure is not described in any of the cited references and one of ordinary skill in the art would not have the proper rationale in arriving at such an embodiment of the present invention.

Thus, these rejections have been overcome. Reconsideration and withdrawal of these rejections are respectfully requested.

*Conclusion*

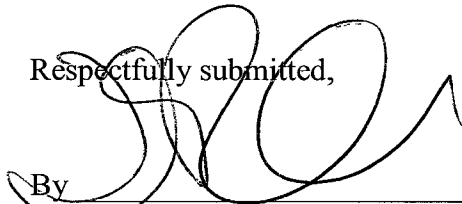
A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,



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